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## **U.S.** House of Representatives

Committee on Agriculture

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January 22, 1999

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WILLIAM E. O'CONNER, JR. STAFF DIRECTOR LANCE KOTSCHWAR CHIEF COUNSEL STEPHEN HATERIUS, MINORITY STAFF DIRECTOR

The Honorable Jane Henney, MD Commissioner, Food and Drug Administration 5600 Fishers Lane Rockville, MD 20857

Dear Dr. Henney:

It is our understanding that the Food and Drug Administration's (FDA) Veterinary Medicine Advisory Committee is currently reviewing a proposed framework to significantly modify the approval process for antimicrobials used in animal medicine. We are writing to express concern that the proposed framework may not be based on sound, riskbased scientific assessment.

We also understand that, to date, no comprehensive risk assessment has been conducted to inform and support this important undertaking. We believe that any issue that represents a potentially significant effect on the consumers' food supply and the food production system deserves a thorough, scientifically sound, and transparent rule-making process. Moreover, we believe that efforts to maintain animal health and welfare may be undermined, without a clear understanding of potential human health benefits. Under the circumstances, this seems unwarranted. 5.

Simply put, maintaining the superior safety and quality of our nation's food supply is too important to trust to an incomplete process, where sufficient attention to risk assessment has not occurred. We believe that focusing the necessary attention on data collection and risk assessment up front will result in a better long-term policy; one that will safeguard antibiotic use for both human and animal medicine.

We would appreciate your making our interest in this issue known to the VMAC at their upcoming meeting and hope you will keep us updated as this issue progresses. We look forward to working with you to ensure that American consumers and livestock producers are well served in this process.

Sincerely,

Larry Combest, Chairman

Rep. Charles Stenholm, Ranking Member

Collin Peterson

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